REMARKS

In view of the following remarks, the Office is respectfully requested to allow claims 11, 13-15, 27, 31, and 39-42, the only claims pending and under examination in this application.

Claims 1-10, 12, 16-26, 28-30 and 32-38 stand previously cancelled without prejudice.

Support for the amendment to Claim 11 may be found in the specification at page 8, lines 7 to 16. Claims 39 and 42 are newly added. Support for new claims 39 and 40 may be found in the working exemplification and the previously pending claims, as well as the specification as originally filed. Support for new claims 41 and 42 may be found throughout the specification, such as, for example, at page 6, lines 11 to 25 as well as the experimental data presented in a murine model beginning at page 18, line 14.

As the above amendments introduce no new matter, their entry by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 11, 13-15, 27 and 31 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Fogarty et al. (U.S. Patent No. 6,291,243). The claims require the presence of a p-feet flanked domain of at least 2000 bp comprising a transcriptionally active gent that is less than 1000 bp from one of the p-feet. It is not seen where this element is taught in the cited '243 patent. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 11, 13-15, 27 and 31 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification allegedly does not enable any person skilled in the art to make and use the claimed invention commensurate in scope with the claims.

At page 5 of the Office Action mailed October 2, 2007, however, the Office has indicated that subject matter such as that presented in new claims 39 and 41-42 is enabled by the instant specification. Accordingly, allowance of these claims is respectfully requested.

The rejection as applied to claims 11, 13-15, 27 and 31 is respectfully traversed for at least the following reasons.

In the Office Action mailed October 2, 2007, and previously, the Office has acknowledged that enablement is present for a method of inserting an exogenous nucleic acid into the genome of a **mouse**, comprising:

> "...introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp [*stet:in*] proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element trasposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp [*stet:in*] proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said **mouse**." (Office Action mailed February 27, 2007 at pages 4-5; emphasis added).

The law regarding enablement of inventions is clear: "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation."[1] In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. The Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure.[2]

Further, the test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.[3] The skilled artisan need not be able to predict in advance which modifications will result in successful practice of the claimed method

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[1] *United States v. Telectronics, Inc.*, 8 USPQ 2d 1217, 1233 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). See also *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).
[2] *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).
[3] *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

in rats versus mice. Trial and error experimentation will readily provide this information. As noted by the Federal Circuit, trial and error experimentation is not necessarily undue.[4]

Applicants have amended the claims to specify that the claimed method is performed in a mouse. However, Applicants have also included the rat embodiment in this amendment, based on the disclosure in the Specification at page 19, lines 18-22, wherein it is set forth that male mice and rats were injected into their testis and these animals gave transgenic offspring.

Applicants maintain that the present application provides sufficient disclosure to enable the invention to the full scope of the pending claims with regard to mice and rats. Once transgenesis is demonstrated in one rodent species (mouse) using the P-element derived vectors from such a divergent and unrelated species (*Drosophila* fly of phylum Arthropoda), it is reasonable to conclude that the methods can be extrapolated to other rodents in a similar manner without undue experimentation. Rats are genetically and morphologically nearly identical to the mouse. Therefore, once the Applicants demonstrated the possibility of the described method with one species of rodent, it is reasonable to conclude that such methods can be used to generate transgenic rodents of different species using a vector that comprises a transposase recognized insertion sequence and an exogenous nucleic acid with a reasonable amount of experimentation.

Accordingly, based on the disclosure in the specification, and the knowledge of those skilled in the art at the time of filing, the experimentation involved in selecting a rat or a mouse for use in practicing the claimed method does not rise to the level of "undue experimentation", as analyzed under the factors of *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Thus, Applicants respectfully request that the rejection under U.S.C. § 112, first paragraph, be withdrawn.

Double Patenting

The Office provisionally rejects claims 11, 13-15, 27 and 31 under the judicially-created doctrine of obvious-type double patenting as allegedly unpatentable over claims 11, 13-15, 18, 27, 30-31 and 34 of co-pending Application Serial No. 10/659,802. A terminal disclaimer in compliance with 37 C.F.R. § 3.73(b) is filed herewith. The filing of the terminal disclaimer obviates the rejection and withdrawal is respectfully requested.

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[4] *See, e.g., In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number TOSK-007CIPCON.

Respectfully submitted,
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Enc:
- Terminal Disclaimer over application serial no. 10/659,802

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